

Reconsideration of the above-identified application is respectfully requested in view of the following remarks.

### **REMARKS**

#### ***Status of the Claims***

Claims 17-25 are currently pending. Claims 17-25 have been rejected.

#### ***Rejections under 35 U.S.C. § 103***

(1) The Examiner has rejected claims 17-21, 23 and 25 under 35 U.S.C. §103(a) as being unpatentable over Youssefyeh et al. (U.S. Pat. No. 5,968,519) in view of Mantelle et al. (U.S. Pat. No. 6,562,363). Applicant respectfully traverses this rejection.

It is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Applicant respectfully asserts that Youssefyeh et al. does not disclose or suggest all the claim limitations presently claimed, and Applicant submits herewith the Rule 131 Declaration to overcome Youssefyeh et al. and Mantelle et al.

#### **Independent claim 17**

Claim 17 is directed to, “[a] method of treating immunological skin disorders comprising applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier having contained therein a steroid, and hardening the carrier into a tangible, member juxtaposed to said affected area, wherein said film-forming carrier is nitrocellulose.” See claim 17, as presently pending. As previously pointed out, Youssefyeh et al. does not teach or disclose the use of nitrocellulose as the film-

forming carrier, and thus, does not disclose all the claim limitations of the presently claimed invention. In fact, the Examiner has acknowledge as much, stating, “Youssefych [et al.] do not teach that the film-forming carrier is nitrocellulose.” See Office Action at page 5, second paragraph.

Furthermore, Applicant previously submitted the Rule 132 Declaration of Joel Studin with his response of April 24, 2008. As previously pointed out, the Rule 132 Declaration of Joel Studin shows a comparison of transdermal effectiveness evaluation of various possible film-forming carriers for delivering topical treatments such as corticosteroids. See the Rule 132 Declaration of Joel Studin, submitted with Applicant’s response on April 24, 2008. According to the Rule 132 Declaration, Nitrocellulose (Flexible Collodion) had the highest blanching test score of 141, and nitrocellulose (flexible collodion/xanthan gum) has the second highest test score with a 59. Again, the higher the score, the higher the degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested. See the Rule 132 Declaration submitted April 24, 2008, at paragraph 8; see also Exhibit A at page 6. The Examiner is kindly directed to the bottom of page 6 of Exhibit A, which states, “[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.” Therefore, Applicant respectfully asserts that use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers.

The Examiner has cited Mantelle et al. to overcome the deficiencies of Youssefych et al. According to the Examiner, “Mantelle et al. (\*363) teach

bioadhesive compositions in a flexible, finite form for topical application to skin or mucus membranes and methods for topical administration of active ingredients.”

However, Applicant submits herewith the Rule 131 Declaration of Joel Studin to overcome Mantelle et al. As shown by the Rule 131 Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to December 3, 1996. See Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of the Mantelle et al. reference (September 26, 1997), Mantelle et al. is no longer an effective reference against the invention as claimed.

As previously pointed out, Youssefeyh et al. does not disclose or suggest the use of nitrocellulose as the film-forming carrier, and thus, does not and cannot render obvious claim 17. Likewise, claim 18, which depend from claim 17, is not rendered obvious by Youssefeyh et al. Reconsideration and withdrawal of this rejection is respectfully requested.

#### Independent claim 19

Claim 19 has been amended to recite, “[a] composition for treating adverse skin conditions comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof, said carrier capable of hardening to a tangible member, wherein said film-forming carrier is nitrocellulose.” See claim 19, as presently pending.

Again, Applicant respectfully directs the Examiner's attention to the Rule 131

Declaration of Joel Studin, submitted herewith. As shown by the Rule 131

Declaration, Joel Studin invented the presently claimed invention prior to the earliest priority dates of Youssefych et al. (December 3, 1996) and Mantelle et al. (September 26, 1997). According to the Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to December 3, 1996. See the Rule 131 Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of both Youssefych et al. (December 3, 1996) and the Mantelle et al. reference (September 26, 1997), Youssefych et al. and Mantelle et al. are no longer effective references against the invention as claimed.

Reconsideration and withdrawal of this rejection are respectfully requested.

(2) The Examiner has rejected claims 17-21, 23 and 25 under 35 U.S.C. §103(a) as being unpatentable over Youssefych et al. (U.S. Pat. No. 5,968,519) in view of Brandt et al. (U.S. Pat. No. 6,627,216). Applicant respectfully traverses this rejection.

Applicant respectfully asserts that Youssefych et al. does not disclose or suggest all the claim limitations presently claimed, and Applicant submits herewith the Rule 131 Declaration to overcome Youssefych et al. and Brandt et al.

Independent claim 17

Applicant again respectfully points out that claim 17 is directed to, “[a] method of treating immunological skin disorders comprising applying onto an area of skin affected by said skin disorder a fluid, film-forming carrier having contained therein a steroid, and hardening the carrier into a tangible, member juxtaposed to said affected area, wherein said film-forming carrier is nitrocellulose.” See claim 17, as currently amended (emphasis added). Applicant respectfully asserts that Youssefeyh et al. does not teach or disclose the use of nitrocellulose as a film-forming carrier, and thus, does not disclose all the claim limitations of the presently claimed invention. The Examiner has acknowledged as much, stating, “Youssefeyh [et al.] do not teach that the film-forming carrier is nitrocellulose.” See Office Action at page 6, second full paragraph. Again, Applicant respectfully asserts that Youssefeyh et al. does not teach or suggest the use of nitrocellulose as a film-forming carrier.

The Examiner has cited Brandt et al. to overcome the deficiencies of Youssefeyh et al. More specifically, according to the Examiner, “Brandt et al. (‘216) teach fluid compositions that are coated onto the surface of a host animal and then dried to form a covering element, such as a transdermal bandage, patch or the like (col. 1, lines 7-21). The fluid compositions include film-forming polymeric components of cellulosic polymers such as nitrocellulose.” See Office Action at page 6, third full paragraph.

However, Applicant respectfully directs the Examiner’s attention to the Rule 131 Declaration of Joel Studin, submitted herewith. As shown in the Rule 131 Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to

December 3, 1996. See Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of the Brandt et al. reference (August 20, 1998), Brandt et al. is no longer an effective reference against the invention as claimed.

As previously pointed out, Youssefeyeh et al. does not teach or disclose the use of nitrocellulose as the film-forming carrier, and thus, does not and cannot render obvious claim 17. Likewise, claim 18, which depend from claim 17, is not rendered obvious by Youssefeyeh et al. Reconsideration and withdrawal of this rejection is respectfully requested.

Independent claim 19

As previously pointed out, claim 19 has been amended to recite, “[a] composition for treating adverse skin conditions comprising a fluid, film-forming carrier and an active ingredient comprising a topically active steroid or, a silicone-gel or mixture thereof, said carrier capable of hardening to a tangible member, wherein said film-forming carrier is nitrocellulose.” See claim 19, as presently pending.

Again, Applicant respectfully directs the Examiner’s attention to the Rule 131 Declaration of Joel Studin, submitted herewith. As shown by the Rule 131 Declaration, Joel Studin invented the presently claimed invention prior to the earliest priority dates of Youssefeyeh et al. (December 3, 1996) and Brandt et al. (August 20, 1998). According to the Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to December 3, 1996. See Declaration at section 5. In as

much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of both Youssefeyh et al. (December 3, 1996) and the Brandt et al. reference (August 20, 1998), Youssefeyh et al. and Brandt et al. are no longer effective references against the invention as claimed. Reconsideration and withdrawal of this rejection are respectfully requested.

(3) The Examiner has rejected claims 22 and 24 under 35 U.S.C. §103(a) as being unpatentable over Youssefeyh et al. (U.S. Pat. No. 5,968,519) in view of Herb et al. (U.S. Pat. No. 5,534,246). Applicant respectfully traverses this rejection.

As previously pointed out hereinabove, independent claim 19, from which claims 22 and 24 depend, recites, “wherein said film-forming carrier is nitrocellulose.” See claim 19, as presently pending (emphasis added). It is well established that to render a claimed invention obvious all the claim limitations must be taught or suggested by the prior art. As Applicant has previously pointed out, although Youssefeyh et al. discloses the use of a film-forming carrier, Youssefeyh et al. does not disclose the use of nitrocellulose as a film-forming carrier.

The Examiner cites Herb to overcome the deficiencies of Youssefeyh et al. More specifically, according to the Examiner, “Herb et al. also teaches that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect of for adjusting the refractive index.” See Office Action at page 7. However, like Youssefeyh et al., Herb et al. does not disclose the use of nitrocellulose as a film-forming carrier, and thus, the combination of Youssefeyh et al. with Herb et al. does not disclose all the claim limitations of the presently claimed invention.

Again, Applicant submitted with his response on April 24, 2008, the Rule 132 Declaration of Joel Studin along with Exhibit A, showing a comparison of transdermal effectiveness evaluation of various possible film-forming carriers for delivering topical treatments such as corticosteroids. Nitrocellulose (Flexible Collodion) had the highest blanching test score of 141, and nitrocellulose (flexible collodion/xanthan gum) has the second highest test score with a 59. Again, the higher the score, the higher the degree of blanching, and thus, the highest degree of transdermal transmission of the active agent (hydrocortisone) tested. See Declaration paragraph 8; see also Exhibit A at page 6. The Examiner is kindly directed to the bottom of page 6 of Exhibit A, which states, “[m]ost carriers showed very poor transdermal transmission of the active. Nitrocellulose however, showed a very strong transmission in our formulation... [i]t is our suggestion that you continue the development of your products using the nitrocellulose base that you suggested.” Therefore, Applicant respectfully asserts that use of nitrocellulose as the film-forming carrier shows a superior level of blanching of hydrocortisone into the skin when compared to other film-forming cellulose carriers.

As such, Applicant respectfully asserts that the combination of Youssefych et al. with Herb et al. does not and cannot render claims 17, 19-21 and 23-29 obvious. Reconsideration and withdrawal of this rejection is respectfully requested.

(4) The Examiner has rejected claims 17-21, 23 and 25 under 35 U.S.C. §103(a) as being unpatentable over Mantelle et al. (U.S. Pat. No. 5,446,070) in view of Mantelle et al. (U.S. Pat. No. 6,562,363). Applicant respectfully traverses this rejection.



According to the Examiner, the '070 patent "teaches flexible, finite, bioadhesive compositions for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agent." See Office Action at page 8, second paragraph. However, as the Examiner notes, "Mantelle [the '070 patent] does not teach that the film-forming carrier is nitrocellulose." See Office Action at page 8, sixth paragraph.

The Examiner has cited Mantelle et al. (the '363 patent) to overcome this deficiency. According to the Examiner, the '363 patent teaches "bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients... [p]articularly suitable bioadhesive materials taught include cellulose materials such as nitrocellulose." See Office Action at pages 8-9.

However, Applicant again directs the Examiner's attention to the Rule 131 Declaration of Joel Studin, submitted herewith. As shown by the Rule 131 Declaration, Joel Studin directed Bryce Labs to prepare a composition for treating scars, eczema and psoriasis, containing a steroid (hydrocortisone acetate) in a film-forming carrier (flexible collodion), and apply the formulation to skin, prior to December 3, 1996. See Declaration at section 5. In as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of the Mantelle et al. reference (September 26, 1997), Mantelle et al. is no longer an effective reference against the invention as claimed.

As previously pointed out, the '070 patent does not teach or disclose the use of nitrocellulose as the film-forming carrier, and thus, does not and cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection is respectfully requested.

(5) The Examiner has rejected claims 17-21, 23 and 25 under 35 U.S.C. §103(a) as being unpatentable over Mantelle et al. (U.S. Pat. No. 5,446,070) in view of Brandt et al. (U.S. Pat. No. 6,627,216). Applicant respectfully traverses this rejection.

Again, Mantelle et al. (the '070 patent) does not disclose the use of nitrocellulose as the film-forming carrier. The Examiner acknowledges as much, stating, "Mantelle [et al.] do not teach that the film-forming carrier is nitrocellulose." See Office Action at page 9, second to last paragraph.

The Examiner has cited Brandt et al. to overcome this deficiency. More specifically, according to the Examiner, Brandt et al. teaches the use of nitrocellulose as a film-forming carrier. However, as previously pointed out, Applicant has submitted herewith the Rule 131 Declaration of Joel Studin to overcome Brandt et al. As previously pointed out, in as much as the Applicant has reduced the present invention to practice (a formulation containing a steroid and a film-forming carrier and applied it to skin), prior to the earliest effective date of the Brandt et al. reference (August 20, 1998), Brandt et al. is no longer an effective reference against the invention as claimed. As such, Applicant respectfully asserts that Brandt et al. cannot be properly cited against the present application.

Furthermore, as pointed out hereinabove, Mantelle et al. (the '070 patent) does not teach or suggest all the claim limitations presently claimed, and thus, does not and

cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection is respectfully requested.

(6) The Examiner has rejected claims 22 and 24 under 35 U.S.C. §103(a) as being unpatentable over Mantelle et al. (U.S. Pat. No. 5,446,070) in view of Herb et al. (U.S. Pat. No. 5,534,246). Applicant respectfully traverses this rejection.

Again, Mantelle et al. (the '070 patent) does not disclose the use of nitrocellulose as the film-forming carrier or the use of phenyltrimethicone. The Examiner acknowledges as much, stating, "Mantelle [et al.] do not teach phenyltrimethicone." See Office Action at page 10, third paragraph.

The Examiner cites Herb to overcome the deficiencies of Mantelle et al. More specifically, according to the Examiner, "Herb et al. also teaches that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect of for adjusting the refractive index." See Office Action at page 7. However, like Mantelle et al., Herb et al. does not disclose the use of nitrocellulose as a film-forming carrier, and thus, the combination of Mantelle et al. with Herb et al. does not disclose all the claim limitations of the presently claimed invention.

As such, Applicant respectfully asserts that the combination of Mantelle et al.  
with Herb et al. does not and cannot render claims 22 and 24 obvious.  
Reconsideration and withdrawal of this rejection is respectfully requested.

Respectfully submitted,

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Date

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